

## REMARKS

In the Official Action dated June 3, 2002, claims 18-20, 25 and 26 stand rejected.

Amended claims 18-26 and new claims 27-31 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Gorman, European Patent Application No. 0 260 148 (hereinafter "Gorman") in view of Builder et al., U.S. Patent No. 5,663,304 (hereinafter "Builder et al."), Meulien, U.S. Patent No. 5,521,070 (hereinafter "Meulien"), Ritter et al., (1991) J. Biol. Chemistry 266:1043-1047 (hereinafter "Ritter et al.") and Ciotti et al. (1996) Biochemistry 35:10119-10124 (hereinafter "Ciotti et al.").

This response addresses the Examiner's rejection. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Applicants, through the undersigned, wish to thank the Examiner Katcheves for the courtesy and assistance provided in connection with a telephonic interview conducted on September 20, 2002.

Claims 18-20, 25 and 26 and new claims 27-31 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Gorman in view of Builder et al., Meulien, Ritter et al. and Ciotti et al. The Examiner alleges that the cited references together teach the claimed invention. The Examiner further alleges that motivation to combine the asserted references exists inasmuch as Gorman allegedly teaches production of biological factors in Sertoli cells.

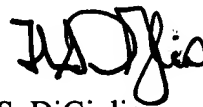
Applicants respectfully submit that the cited references fail to teach or suggest the invention, as presently claimed. Notably, none of the cited references recognize a Sertoli cell comprising a vector which functions in a Sertoli cell operatively linked to a coding sequence for a biological factor wherein the Sertoli cell creates an immunologically privileged site *in vivo*.

Assuming, pro arguendo, the generalized teachings of Sertoli cells and vectors in the cited references, Applicants submit that there is simply no suggestion or motivation to construct a Sertoli cell which comprises a vector comprising a promoter operably linked to a coding sequence for a biological factor, wherein the Sertoli cell creates an immunologically privileged site *in vivo*. The genetically altered Sertoli cells of the present invention provide an immunologically privileged site *in vivo* as measured, for example, by functional assessment of the biological factor produced by the cells. The cited references fail to appreciate, no less motivate the skilled artisan to create altered Sertoli cells, as claimed. Support for the *in vivo* immunoprivileged environment is found throughout the specification and particularly at page 6, lines 14-17, for example; in full satisfaction of the requirements of 35 U.S.C. §112, first paragraph.

Accordingly, the rejection of claims 18-20, 25, 26 and new claims 27-31 under 35 U.S.C. §103(a) is overcome and withdrawal thereof is respectfully requested.

Thus, in view of the foregoing amendments and remarks, it is believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Frank S. DiGiglio  
Registration No. 31,346

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343

PIB:dg